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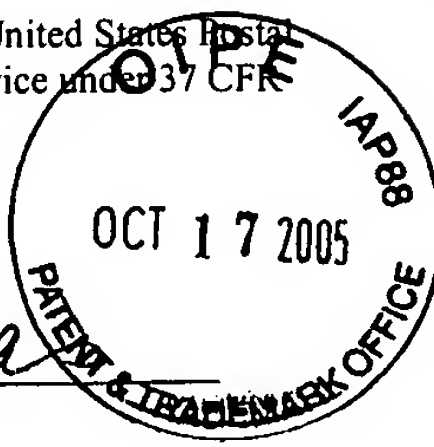
PATENT

Attorney Docket No.: 010692-004532US

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By: Marta Vanegas



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gorfine, Stephen R.

Application No.: 10/669,099

Filed: September 22, 2003

For: NITRIC OXIDE DONOR
COMPOSITION AND METHOD FOR
TREATMENT OF ANAL DISORDERS

Examiner: Tate, Christopher Robin

Art Unit: 1654

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the U.S. patent references (Ref. Nos. 1-24) are not submitted [in compliance with the requirements of 1287 OG 163].

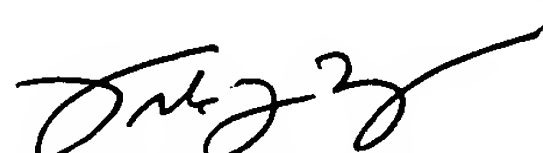
In accordance with 37 CFR 1.95(d), copies of foreign patent Ref. Nos. 25-34 and non-patent Ref. Nos. 38-76 are to be found in U.S. Patent Appln. Nos. 08/250,555 (filed May 27, 1994, Patent No. 5,504,117, Atty. Ref. 010692-004500US); 08/371,088 (filed Jan. 10, 1995, abandoned, Atty. Ref. 010692-004510US); 08/666,264 (filed Jun. 20, 1996, Patent No. 5,693,676, Atty. Ref. 010692-004520US); 08/970,447 (filed Nov. 14, 1997, abandoned, Atty. Ref. 010692-004530US); and 10/021,168 (filed Dec. 11, 2001, abandoned, Atty. Ref. 010692-

004531US). Additional copies of these references may be provided to the Examiner upon request. Copies of the remaining references (Ref. Nos. 33-35 and 77-104) are submitted herewith. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

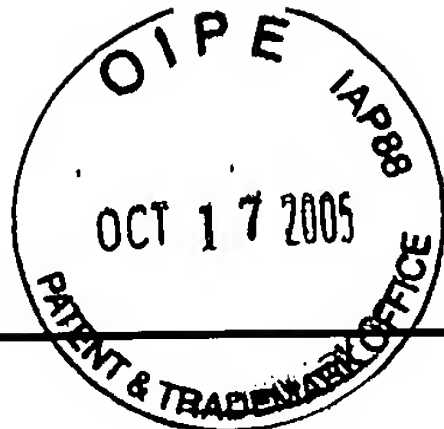
This Statement is submitted concurrently with a Request for Continued Examination. Accordingly, no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft
Reg. No. 46,946

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60610458 v1



PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1654
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	1	US-814,408	03-06-1906	Steele	
	2	US-2,840,080	06-24-1958	Clark	
	3	US-3,419,571	12-31-1968	Di Carlo et al.	
	4	US-4,118,480	10-03-1978	Williams	
	5	US-4,226,849	10-07-1980	Schor	
	6	US-4,292,299	09-29-1981	Suzuki et al.	
	7	US-4,371,516	02-01-1983	Gregory et al.	
	8	US-4,514,384	04-30-1985	Gallina	
	9	US-4,608,249	08-26-1986	Otsuka et al.	
	10	US-4,654,209	03-31-1987	Leslie et al.	
	11	US-4,657,906	04-14-1987	Emmet et al.	
	12	US-4,683,242	07-28-1987	Poser	
	13	US-4,746,675	05-24-1988	Makino et al.	
	14	US-4,842,854	06-27-1989	Babaian et al.	
	15	US-5,047,230	09-10-1991	Nagy et al.	
	16	US-5,059,603	10-22-1991	Rubin	
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	19	US-5,439,938	08-08-1995	Snyder et al.	
	20	US-5,504,117	04-02-1996	Gorfine	
	21	US-5,508,045	04-16-1996	Harrison et al.	
	22	US-5,595,753	01-27-1997	Hechtman	
	23	US-5,595,970	01-21-1997	Garfield et al.	
	24	US-5,693,676	12-07-1997	Gorfine	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	25	DE	304,730	03-01-1989	Dunzendorfer et al.		<input type="checkbox"/>
	26	AU	74545/94	08-19-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	27	AU	PM 0971	03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	28	AU	PM 4247	03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	29	AU	PM 6395	07-14-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
	30	DE	4,038,203	06-04-1992	Bonnacker et al.		<input type="checkbox"/>
	31	JP	62-67017	03-26-1987	Sawai et al.		<input type="checkbox"/>
	32	WO	98/36733	08-27-1998	Kamm, Michael Albert et al.		<input type="checkbox"/>

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60610458 v1

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
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				Examiner Name	Tate, Christopher Robin
Sheet	2	of	7	Attorney Docket Number	010692-004532US

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		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	33	WO	95/06466	A1	03-09-1995	Koren Laboratories Pty., Ltd.		
	34	ZA	77/01135		02-25-1977	Prinsloo, J.		
	35	JP	04-091036		03-24-1996	Hashioka Tatsuya		
	36	WO	87/03490		06-18-1987	Key Pharmaceuticals, Inc.		
	37	WO	98/37886		09-03-1998	Antropoli		

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NON PATENT LITERATURE DOCUMENTS			
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	38	Ahlner et al., "Organic Nitrate Esters: Clinical Use and Mechanisms of Actions." <i>Pharmacol. Reviews</i> 43(3):351-353 (1991).	
	39	Budavari et al. (Eds.), "The Merck Index." pp. 198 and 821 (isopropyl nitrate); 11th Edition, Merck & Co., Rahway, N.J. (1989)	
	40	Bult et al., "Nitric oxide as an inhibitory non-adrenergic non-cholinergic neurotransmitter." <i>Nature</i> , 345:346-347, 1990.	
	41	Burleigh, D. and D'Mello, A., "Physiology and Pharmacology of the Internal Anal Sphincter." Chapter 2, pages 22-41, in <i>Coloproctology and The Pelvic Floor</i> , Henry and Swash (Eds.), Butterworth Publishers, Stoneham, Mass., USA and London, England, ISBN 0-407-00352-5 (1985)	
	42	Burleigh, D., "Ng-Nitro-L-Arginine Reduces Nonadrenergic Relaxations of Human Gut." <i>Gastroenterology</i> , 102: 679-683 (1992)	
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	51	Guillemot et al., "Nitroglycerin In Situ Reduces Upper Anal Canal Pressure." <i>Digest. Dis. Sci.</i> , 37(1):155 (1992)	
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	53	Huff et al., (Eds.), "Physicians' Desk Reference." 41st Edition, Medical Economics Company, Oradell, N.J., at pp. 780, 1176-1178, 1533 and 1984-85 (1987)	
	54	Ignarro et al., "Nitric oxide and cyclic GMP formation upon electrical field stimulation cause relaxation of corpus cavernosum smooth muscle." <i>Biochem. Biophys. Res. Commun.</i> , 170:843-850, 1990.	
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	69	O'Kelley, T. <i>et al.</i> , "Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide." <i>Gut</i> , 34: 689-693 (1993)	
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	84	Farouk, R. <i>et al.</i> "Changing patterns of treatment for chronic anal fissure." <i>Annual Review College Surgeons England</i> ; 80:194-6 (1998)	

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	85	"Glyceryl trinitrate for anal fissure?" <i>Drug and Therapeutics Bulletin</i> ; 36:55-6 (1998)	
	86	Gorfine, S.R. "Topical nitroglycerin ointment for anal fissures and ulcers." <i>New England Journal of Medicine</i> ; 333: 1156-7 (1995)	
	87	Hattori, K. et.al. "Fissure treatment in day surgery days." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)	
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	92	Lund JN et al. "Follow-up of patients with chronic anal fissure treated with topical glyceryl trinitrate." <i>Lancet</i> , 352:1681 (1998)	
	93	Lysy, J. et.al. "Treatment of chronic anal fissure with isosorbide dinitrate: long-term results and dose determination." <i>Dis. Col. Rect.</i> , 41:1406-10 (1998)	
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	95	Maria, "Identification of anti-endothelial cell antibodies in patients with chronic anal fissure." <i>Surgery</i> , 126:535-40 (1999)	
	96	Mazier, "Hemorrhoids, fissures, and pruritus ani." <i>Anorectal Surg.</i> , 74(6):1277-92 (1994)	
	97	Oettle, G.J. et.al. "Glyceryl trinitrate vs. sphincterotomy for treatment of chronic fissure-in-ano: a randomized, controlled trial." <i>Dis. Col. Rect.</i> , 40:1318-20 (1997)	
	98	Pitt, J. et.al. "Chemical sphincterotomy for anal fissure." <i>Colorectal disease</i> 1998; 2-8.	
	99	Pitt, "Double-blind, randomized, placebo-controlled trial of oral indoramin to treat chronic anal fissure." ASCRS Meeting, June 2000, Poster Presentation P2 (2000)	
	100	Romano, "A critical appraisal of pathogenesis and morbidity of surgical treatment of chronic anal fissure." <i>J. Am. Coll. Surg.</i> , 178:600-4 (1994)	

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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	101	Schouten, "Relationship between anal pressure and anodermal blood flow: The vascular pathogenesis of anal fissures." <i>Dis. Col. Rect.</i> , 37(7):664-9 (1994)	
	102	Schouten, "Ischaemic nature of anal fissure." <i>Br. J. Surg.</i> , 83:63-5 (1996)	
	103	Simons, A.J. et al. "Glyceryl trinitrate for anal fissure." <i>Lancet</i> , 348:491-2 (1996)	
	104	Suda, K. et.al. "Application of nitroglycerin ointment on post-hemorrhoidectomy pain." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.